

### REMARKS/ARGUMENTS

Claims 1-20 were pending at the time of the mailing of the final Office Action. Claims 17-20 were previously withdrawn from consideration and are now cancelled without prejudice or disclaimer as to the subject matter contained therein. Additionally, claims 3, 4, 7-9, 11, 12, 14 and 15 are also cancelled without prejudice or disclaimer. The Applicants reserve the right to advance these and similar claims in a divisional or continuation application. By this amendment, claim 1 has been amended to include the elements of claims 3 and 4. No claims have been added.

In the Office Action of June 10, 2011, claims 1-16 were rejected under 35 USC § 103(a) as being unpatentable over Tennikova et al. (J. High Resol. Chromatogr., 2000, 23, 27-38) (hereinafter "Tennikova") in view of U.S. Pat. No. 6,238,565 to Hatch (hereinafter "Hatch") and further in view of U.S. Pat. Pub. No. 2003/0032147 to Sauer et al. (hereinafter "Sauer"). Tennikova was relied upon for the teaching of a monolith structure containing macropores continuously extending from one end to another. Hatch was alleged to provide a monolith structure varied by the size of the nucleic acids to be purified. Sauer was cited as providing a teaching of the use of potassium ions for adsorbing nucleic acids onto the monolith and eluting them with a salt free solution.

In the Office Action, the teaching of a monolith structure varied by the size of the nucleic acids to be purified was alleged to be shown by Hatch's disclosure of the need for "an interstitial distance" of 1  $\mu\text{m}$  for separation of a 300 bp long DNA segment and "an interstitial distance" of about 1 to 3  $\mu\text{m}$  for separation of a 1000 bp long DNA segment. However, the "interstitial distance" being discussed in this portion of Hatch (the Background of the Invention section) clearly relates to prior column chromatography techniques. The "interstitial distance" is the distance between particles in a packed bed separation column. Regarding an interstitial distance of 1-3  $\mu\text{m}$ , Hatch states, "Columns with packing of 3-10 micrometers in diameter would provide such distances." (Column 3, lines 44-45). Additionally, Hatch provides "columns packed with very small particles, such as 1 micrometer diameter, could be useful for samples up to 300 base pairs in

length". (Column 3, lines 50-52). Clearly, this does not teach the use of different pore sizes in a monolith structure but rather teaches different spacing between particles in a traditional, packed bed chromatography column.

Furthermore, Hatch teaches away from applying the lessons of column chromatography to monolith structures. "The above theory relating to beds of packed particles is not particularly useful for predicting the behavior of macromolecules in continuous monolithic beds, where mass transport may be a combination of diffusive and convective processes." (Column 3, line 57-61). Additionally, Hatch teaches, "Moreover, the monolithic columns of the present invention can be constructed with stationary phase geometries significantly different than those available with packed beds. The effects of such novel geometries on the separation of macromolecules have not been predicted so far by current chromatographic theory." (Column 4, line 9-14). Therefore, Hatch itself teaches that the disclosures cited in the Office Action regarding interstitial spacing in column chromatography are not applicable to monolith columns.

The Applicants reiterate their previous argument that Hatch does not actually teach or suggest selecting the size of the macro-pores in the monolith according to the size of the nucleic acid molecule to be purified. Hatch only provides for the separation of nucleic acids with one composition for nucleic acids of 17 base pairs to 3 kilobase pairs (Column 8, lines 5-8 and 20-21.) Hatch only teaches, "the high resolution made possible by the present invention is preserved for columns with pores up to at least about 170 times the length of the DNA molecules to be separated." (Column 8, line 23-26). Hatch therefore, does not teach or suggest selecting the diameter of macropores in the monolith according to the size of the nucleic acid to be purified.

Furthermore, Hatch does not teach or suggest the presence of micropores within the macropores as recited in amended claim 1. Hatch only discloses one set of macropores, "...the present invention will have pores in the less than 5,000 nm range, down to about 10 nm (column 8, line 2-3)." This does not teach or suggest micro-pores

within macro-pores as recited in the instant claims. Additionally, neither Tennikova nor Sauer is observed to provide such a teaching or suggestion.

Therefore, none of the cited prior art, alone or in combination, teaches or suggests all the elements of claim 1, and claims 1, 2, 5, 6, 10, 13 and 16 patentably distinguish over Tennikova in view of Hatch in further view of Sauer. Withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully respected.

Accordingly, the Applicants maintain that the claims patentably distinguish over the prior art and are in condition for allowance. The issuance of a Notice of Allowance is earnestly solicited.

The outstanding Office Action was mailed on 10 June 2011. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, a petition for a three month extension of time is hereby made with this response. This response is timely filed on December 12, 2011, with a three month extension of time as the time period for response ended on Saturday, December 10, 2011. December 12, 2011 is the next business day following a deadline for response which falls on a Saturday, Sunday or federal holiday. The Commissioner is authorized to charge any fee or to credit any overpayment associated with the filing of this paper to Deposit Account 15-0450.

Respectfully submitted,

/John J. Cunniff/

John J. Cunniff  
Reg. No 42,451  
Hahn Loeser + Parks LLP  
One GOJO Plaza  
Suite 300  
Akron, OH 44311

Attorney for Applicants